The Premier Research Quality Assurance Professional Organization

25 February 2002

Via UPS

U.S. Environmental Protection Agency Enforcement and Compliance Docket and Information Center Mail Code 2201A Attn: Docket Number EC-2000-007 1200 Pennsylvania Avenue NW Washington, DC 20460 Received

FEB 26 2002

Enforcement & Compliance Docket & Information Center

Re: Society of Quality Assurance (SQA) comments/Docket Number EC-2000-007

Dear Sir/Madam:

The Society of Quality Assurance (SQA) is pleased to comment on the Agency's proposed Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR), which was published in the 66 Federal Register 46162 (31 August 2001). SQA is composed of quality assurance and other professionals who support work that is conducted according to Good Laboratory Practices (GLPs), Good Clinical Practices (GCPs), and Good Manufacturing Practices (GMPs). Some of our members work specifically with studies that are submitted to the Environmental Protection Agency (EPA) and/or with studies that are submitted to the Food and Drug Administration (FDA). Many of our members are familiar with, and must comply with, FDA's 21 CFR Part 11, "Electronic Records; Electronic Signatures." Therefore, we welcome the efforts of the EPA to move in a direction that narrows the gap between regulatory requirements for EPA and FDA registrations. Enclosed with this letter, SQA respectfully submits its comments for your consideration. The comments on CROMERRR are arranged in order of presentation in the Preamble and the Rule itself.

During the 11 July 2002 CROMERRR public meeting in Washington, DC, a recommendation was made that an industry working group be formed after publication of the proposed CROMERRR. The purpose of the CROMERRR working group would be to collaborate to resolve issues (including those with unique characteristics), prior to publication of the final CROMERR Rule. We urge EPA to form this working group and include participation from all stakeholders. Stakeholders from companies submitting registration applications to EPA under the FIFRA and TSCA GLP programs could be represented by members of SQA. Representatives familiar with 21 CFR Part 11 should also be included in the working group. If the Agency would like to pursue the formation of a working group, please feel free to contact me. Other potential stakeholders might be represented by such organizations as Croplife America (formerly known as the American Crop Protection Association), the American

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Chemistry Council (ACC, formerly known as the Chemical Manufacturers Association), the American Petroleum Institute (API), Association of Public Health Laboratories (APHL), Synthetic Organic Chemical Manufacturers Association (SOCMA), National Paint & Coatings Association (NCPA), Screen Printing and Graphic Imaging Association International (SPGIAI), Association of State Drinking Water Administrators (ASDWA), Association of Metropolitan Water Agencies (AMWA), Aerospace Industries Association (AIA), and/or members of industry consultants and other parties.

We look forward to participating in what promises to be a process that results in a Final Rule that meets the Agency's needs for managing and receiving electronic documents and facilitates industry's ability to comply in a timely fashion.

Sincerely,

Kathleen O BarrowcloyL

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Society of Quality Assurance Comments

CROMERRR/Docket No. EC-2000-007

25 February 2002

SUMMARY

EPA's Cross-Media Electronic Reporting and Record-Keeping Rule (CROMERRR), published in the <u>Federal Register</u> on 31 August 2001 (Vol. 66 <u>FR</u> No. 170, pp. 46162-46194), is described by EPA as 'allowing' electronic reporting and electronic record-keeping for 40 CFR regulated entities, as prescribed by the Government Paperwork Elimination Act (GPEA) [Public Law 105-277].

In keeping with the GPEA requirements, EPA states in the summary to CROMERRR, "Under today's proposal, electronic document submission or electronic record-keeping will be totally *voluntary*...."

SQA believes EPA's assertion that CROMERRR's record-keeping requirements are "voluntary" may be true in the sense that regulated entities are not required to keep records electronically. However, since electronic record-keeping is the norm for GLP-regulated entities and other Title 40 regulated entities alike, it is not a viable business decision to revert to paper. The EPA FIFRA and TSCA GLP regulated entities have nearly universal electronic record-keeping practices that preclude reverting to paper records and support SQA's position that the "voluntary" aspect of CROMERRR exists only in theory.

The stringent criteria for maintaining electronic records in a 'one size fits all' manner, whereby all electronic records maintained for the purposes of meeting Title 40 program requirements must meet the same criteria, whether an environmental monitoring system, a toxicology data collection system, a policy record, or an indexing tool, impose added cost and burden to regulated entities, rather than removing obstacles to electronic record-keeping. Perhaps consideration could be given to classifying electronic record-keeping systems in some way that takes into account the purpose of the record, whether data are manipulated or processed in the system, and whether the data collection is a continual monitoring process or a process with finite endpoints.

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In the area of archiving records for the entire record retention period, SQA suggests that EPA re-evaluate existing record retention times. The current record retention period for FIFRA registration data can be as long as thirty years, if not longer. Given the rate of technological advances, this would require numerous costly data migration exercises that would place a significant financial burden on regulated entities. Additionally, SQA recommends that EPA acknowledge the need for industry and the Agency to work toward acceptable solutions for archiving without penalizing regulated entities for not having achieved compliance with this requirement.

SQA concludes that the appropriate course of action is for EPA to decouple the record-keeping portion of the proposed rule from the reporting portion to allow for adequate consideration of existing technology, record retention requirements, the pervasiveness of electronic record-keeping, and the degree of security and control required based on the type and impact of the electronic records. This decoupling would allow EPA to enable electronic reporting, as mandated by the GPEA, while re-evaluating the electronic record-keeping requirements. SQA believes there are varying levels of security and system controls for electronic record-keeping systems based on the type data being collected and maintained, the reason for keeping the data, the critical impact on the environment associated with data integrity, the cost and quality benefits, and the acceptability of procedural controls in managing the data.

DISCUSSION

Preamble header lists the following: 40 CFR Parts 3, 51, 60, 63, 70, 123, 142, 145, 162, 233, 257, 258, 271, 281, 403, 501,745, and 763.

The Preamble Summary states "EPA will only begin to accept direct submission of an electronic document ... and will only begin to allow electronic records to satisfy a specific EPA record-keeping requirement once EPA has provided public notice stating that such documents and records will satisfy the identified requirement."

- §3.2 (b) Electronic record-keeping...: "An electronic record may satisfy any requirement in this Title provided that (1) it satisfies the requirements of 3.100 and (2) that EPA has published a notice in the Federal Register announcing that EPA is prepared to recognize electronic records under the named Part or Subpart of this Title."
- (1) Comment 1: Chapters 160, 792, and 169 are not listed in the proposed rule. Please clarify the intention of the Rule regarding Chapters that are not listed in the header. Clearly define the scope of the rule, and whether all Chapters require notice in the Federal Register or if some Chapters can already submit electronic records and/or maintain records electronically.

Justification: It is not clear that all Title 40 Chapters are covered by CROMERRR.

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(2) Comment 2: Many organizations and businesses are currently maintaining electronic records and some are performing electronic submissions per the individual EPA program rules and guidelines. A literal reading of the rule indicates EPA will notify organizations when they can initiate submissions and/or record-keeping, but does not mention if current electronic submissions and record-keeping should continue. Please clarify the CROMERRR status for electronic record-keeping and submissions currently in use.

Justification: Many organizations are already maintaining electronic records for Parts 160 and 792 and need guidance on the status of this practice. Clarification will eliminate confusion for industry as it attempts to comply with CROMERRR standards.

I Overview B. What will the proposed regulations do?

(3) Comment 1: According to EPA FIFRA and TSCA GLP, there are "other" records that relate to the predicate rule that are required to be maintained – in addition to the GLP data used to report the results in a final report that is part of a submission to EPA. Examples of these records are: facility records (temperature, humidity, light cycle, entry tracking, etc.), master schedules listing the status of GLP studies, equipment maintenance/repair/calibration records, training records, and standard operating procedures (SOPs). These "other" records may be a combination of electronic and/or paper records. We recommend that CROMERRR clarify whether these "other" EPA FIFRA and TSCA GLP records fall under CROMERRR.

Justification: It is unclear whether the "other" records (electronic and/or paper) that are not included in reports to EPA required under EPA FIFRA and TSCA GLP are meant to be included as part of CROMERRR.

I Overview B. "For regulated entities that choose to keep records electronically, today's proposal requires the adoption of best practices for electronic records management."

(4) **Comment 1:** SQA recommends that EPA clarify the term "best practices for electronic records management". While "best practices" are generally followed by many organizations, the specific procedures vary considerably among organizations. For example backup, migration, acceptance testing and validation/revalidation details, timing and internal procedures can vary widely according to organization, equipment, expertise, personnel resources, culture and procedures. One way to handle this might be for EPA to employ a term such as "adequate best practices" to leave the topic open-ended for interpretation.

Justification: The development and maintenance of electronic records, processes and systems represent a significant investment for regulated entities. Clearly stated expectations that allow regulated entities to develop appropriate plans to meet compliance expectations in the specified timeframe will facilitate implementation of CROMERRR.

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II. Background

B. How would today's proposal change EPA's current electronic reporting policy?

"In terms of electronic signature technology, while we may continue to allow PIN-based approaches, our plan is to emphasize digital signatures based on 'public key infrastructure' (PKI) certificates, given the increasing support for - and acceptance of - PKI for commercial purposes."

(5) Comment 1: EPA states in the preamble that the proposed rule will be technology neutral. However, by emphasizing PKI as a technological path, EPA appears to be recommending a specific technology. Please clarify EPA's intent concerning PKI, i.e., whether this is an example or if EPA expects to require this approach.

Justification: Discussions with IT personnel suggest PKI implementation is a major effort with legal ramifications for data ownership and patent issues. Nesting signatures during data collection, report generation and registration submission requires careful planning. Technology is constantly changing for implementing PKI and requires costly software purchase, implementation and support. Corporate purchase and dissemination of PKI certificates is much less costly than the individual plan proposed by EPA and avoids the data ownership issues. The expense is still significant because of the need to renew licenses for PKI software.

II. Background

E. What Information is EPA seeking about electronic reporting and record-keeping proposals?

"...EPA has, at least, the following three goals:

1. to reduce the cost and burden of data transfer and maintenance...

2. to improve the data...

- 3. to maintain or improve the level of corporate and individual responsibility..."
- (6) Comment 1: Please clarify the intent of the phrase "...to improve the data..." This section implies electronic records might be used to meet higher standards.
- (7) Comment 2: Please clarify the intent of the phrase "...improve the level (of) responsibility...." The phrase implies a deficiency of corporate and individual responsibility in spite of adequate EPA fraud sanctions for compromising data and reporting integrity.

Justification: Improvement of data quality and accountability will almost certainly cost more than merely trying to meet the paper standard and should be addressed in the impact assessment. Perhaps the term "data process improvement" is a preferred term considering the search, access and data analysis options available with electronic systems.

Additionally, it appears the EPA is choosing the "electronic standard" contrary to the "paper standard" under 21 CFR 11. The FDA focused on this to justify the cost of the regulation, the "voluntary" use of electronic records, and the controls required under the rule.

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The EPA, however, seems to admit electronic records might be used to meet higher standards. If electronic records meet a higher standard and the data quality is perceived as "better," does that put firms that voluntarily choose to use paper records at a disadvantage?

Improvement of data quality and accountability will almost certainly cost more than merely trying to meet the paper standard and should be addressed in the impact assessment.

II. E. What information is EPA seeking about electronic reporting and record-keeping proposals?

"EPA is seeking comment whether today's proposal will make electronic reporting and record-keeping a practical and attractive option for smaller regulated entities, especially small business."

(8) Comment 1: Small companies that perform work under EPA FIFRA or TSCA GLPs have embraced electronic systems for data collection and recording in order to utilize modern methods and to increase productivity. If these systems are not CROMERRR compliant, or are not capable of becoming CROMERRR compliant, these small companies must incur additional costs for equipment upgrades, or return to paper-based systems. In fact, some analytical methods cannot be performed without the use of computer-based systems. In such cases, there is no "paper option." These alternatives, lack of an equivalent paper-based system and additional equipment costs, create significant business obstacles for small companies. Electronic record-keeping requirements present a significant challenge for small business.

Justification: Many smaller companies performing work under FIFRA GLPs have fewer than five employees. The cost of purchase, use and maintenance of potentially complex and costly computer systems, including implementation of an archive and/or data/record migration system, may impact the ability of small companies to achieve regulatory compliance. Small companies may not be able to absorb the costs of CROMERRR compliance as readily as larger companies, and may be unfairly disadvantaged in the marketplace.

(9) Comment 2: Since this is a "voluntary" rule, does industry have the option of collecting data using electronic means, printing a hard copy, and defining the printout as the raw data? We recommend that this practice be allowable as an alternative in situations where it makes sense.

Justification: Since the reality is that electronic capture of data is a standard practice, if industry is not permitted to define the printout from electronic capture as the raw data, the "voluntary" aspect of CROMERRR no longer applies. This will impose an unreasonable burden on industry, as records for many 40 CFR programs are currently captured electronically, while the data may be printed out and archived as hard copy.

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II. E. What information is EPA seeking about electronic reporting and record-keeping proposals?

"EPA is interested in concerns or issues that commenters may wish to raise about the effect that moving from paper to the electronic medium may have on the compliance structure."

(10) **Comment 1:** The EPA Office of Compliance is responsible for monitoring laboratories for compliance with the predicate EPA FIFRA or TSCA GLP rules. EPA's budget restrictions for the past and current years have forced budgetary reductions in EPA's Office of Compliance. Please provide assurance that EPA's Office of Compliance has plans for administering compliance monitoring and guidance activities since the implementation of CROMERRR will require significant EPA resources.

Justification: EPA suffered significant personnel cutbacks in the last decade such that the draft merged FIFRA/TSCA GLPs are "on hold" indefinitely. SQA is concerned that EPA's Office of Compliance will have insufficient resources to train inspectors, provide guidance documents for industry and assure compliance.

(11) Comment 2: Once appropriate record-keeping requirements have been developed, SQA recommends that EPA generate compliance guidance for regulatory inspectors and for the regulated community that is consistent with the following EPA and FDA documents:

FDA Compliance Policy Guide 7353.17 (enforcement Policy: 21 CFR Part 11; Electronic Records; Electronic Signatures); FDA Compliance Program Guidance Manual, Program 7348.808 – Chapter 48 – Bioresearch Monitoring, Good Laboratory Practice (Nonclinical Laboratories); FDA Compliance Program Guidance Manual, Program 7348.808s – Chapter 48 – Bioresearch Monitoring, Good Laboratory Practice Program (Nonclinical Laboratories), EPA Data Audit Inspections; EPA Enforcement Response Policy for the Federal Insecticide, Fungicide and Rodenticide Act Good Laboratory Practice (GLP) Regulations, Envires Ref#: P4073; EPA Final TSCA GLP Enforcement Response Policy, Envires Ref#: P2024.

Justification: Consistency regarding Agency inspection for compliance with FDA 21 CFR Part 11 and CROMERRR will facilitate industry compliance. EPA can maximize resources by exploiting the similarities with FDA's requirements, guidance documents and inspection experience for electronic record keeping systems.

- III. C. EPA believes that receipt of electronically transmitted CBI requires considerably stronger security measures than the initial version of CDX may be able to support, including provisions for encryption.
- (12) **Comment 1:** We believe that confidential business information (CBI) should be transmitted only if the CDX includes provisions for encryption. Furthermore, we believe that all information transmitted over the internet should be encrypted.

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Justification: Without encryption, any information transmitted over the internet will not be secure. One of the key goals stated in this legislation is accountability (trustworthy, reliable and generally equivalent to paper records) for submitted data. Individuals and organizations cannot be held accountable for unsecured data submitted over the internet unencrypted. Hence, encryption will have to be in place regardless of whether or not the data are CBI.

- III. C. Which documents could be filed electronically? EPA seeks comments and advice on priorities for electronic reporting implementation.
- (13) **Comment 1:** In no instance should the transmission of any data/reports/CBI occur until the CDX system has been adequately tested, evaluated and certified as effective and reliable.

Justification: We believe that there needs to be a distinction between electronic reporting of data, electronic record-keeping (directed by predicate rules) and confidential business information (CBI).

We believe that electronic reporting options should be explored first, independent of electronic record-keeping options, which could be potentially non-voluntary due to predicate rule requirements. EPA should work closely with the EPA FIFRA and TSCA GLP regulated parties to understand fully the amount of data required for submission of documents and only implement electronic reporting after case studies have been completely researched. The interaction between the Agency and the EPA FIFRA and TSCA GLP regulated parties should also explore the timing of data submission and the possibility of re-evaluating the Agency's 'one size fits all' approach.

We agree that submission of CBI data is a special category and must only be attempted after careful review and testing of the CDX capabilities, especially for encryption.

- IV. A. EPA... seeks comment on the appropriateness of the time-frame for notice of major changes...and whether it is in the best interest of the EPA and regulated entities to codify these public notice provisions...and whether the different cases are or can be defined with sufficient precision....
- (14) **Comment 1:** We believe that the time frames are appropriate, necessary and should be codified.

Justification: We believe any changes to the CDX design may have unknown implications for different regulated entities and, although EPA will have a strong understanding of the capabilities of the CDX, EPA may not be able to predict its impact on other systems.

Without specified and codified notification and time periods, changing technology could force continuous and frequent changes to the submission process. That could lead to confusion and increased/repeated and unnecessary costs to the EPA as well as the regulated community.

(15) Comment 2: EPA may want to reconsider making judgments on effects of changes and design one system of notification for all regulated parties.

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Justification: One concern of the regulated community is the EPA's assertion that major changes "will not generally include optional upgrades to software, the provision of additional formatting (or other technical) options, or changes to CDX that simply reflect changes to the regulatory reporting requirements that the system is supporting." How will the EPA determine whether or not an upgrade is "optional?" For example, will a considerable business advantage warrant an upgrade? Furthermore, whether an upgrade is truly "optional" can be determined differently by the involved parties.

- IV. B. 1. These criteria are designed to insure that electronic records are trustworthy and reliable, available to EPA and other agencies and their authorized representatives in accordance with applicable federal law, and admissible as evidence in a court of law to the same extent as a corresponding paper record." See also §3.2000 (b) "An acceptable electronic document receiving system must generate data sufficient to prove, in private litigation, civil enforcement proceedings, and criminal proceedings...."
- (16) **Comment 1:** EPA should determine which jurisdiction's admissibility standards will be applied as a minimum requirement.

Justification: Admissibility in court is an understandable goal but implementing an electronic record keeping system that would meet admissibility standards in all 50 states, in all federal courts, and in criminal as well as civil proceedings would be very difficult, if not impossible. Jurisdictional differences in admissibility standards should to be addressed prior to issuance of CROMERRR.

PREAMBLE IV.B. (1) and (2): Regulated entities that use electronic systems to create, modify, maintain, or transmit electronic records will need to employ...EPA's proposed criteria for electronic record-retention systems must: 1) generate and maintain accurate and complete copies of records and documents in a form that does not allow alteration of the record without detection;...

EPA seeks comment on whether these criteria are appropriate; sufficient to ensure that signatures associated with records fulfill their purpose, and whether these criteria are appropriate for the maintenance of electronic records containing *digital* signatures.

(17) **Comment 1:** How will EPA CROMERRR requirements be aligned with FDA Part 11 requirements?

Justification: Many regulated entities are required to comply with electronic records and reporting regulations from both EPA and FDA. Harmonization of these two rules is highly desirable for administration and management purposes, as well as cost containment. However, EPA should not lose sight of the differences in the scope of EPA regulated programs versus the scope of 21 CFR Part 11 FDA regulated programs. While a certain amount of consistency with 21 CFR Part 11 is preferable to having two very divergent sets of criteria, SQA contends that the range of programs impacted by CROMERRR is much broader than the range of programs regulated by 21 CFR Part 11.

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Therefore, SQA recommends a step-wise process that first reconciles the inappropriate 'one size fits all' approach, then determines where it makes sense to apply criteria that are consistent with FDA's 21 CFR Part 11.

(18) Comment 2: Will EPA seek to interpret CROMERRR in a similar way as FDA has interpreted 21 CFR Part 11, regarding compliance expectations and inspection conduct?

Justification: Experience gained in working toward compliance with Part 11 by regulated entities should be applicable to implementation of CROMERRR. For example, technical limitations regarding long term archiving of electronic records have made compliance to Part 11 particularly challenging. Consideration of areas where there may be a gap between Agency expectations and technical capabilities is requested.

- IV. (B)(6) Additional Options...We realize that the electronic records criteria in today's rule are not as detailed as that contained in FDA's 21 CFR Part 11 and seek comments on whether our proposed criteria are sufficient to ensure the authenticity...
- (19) **Comment 1:** Where appropriate, we recommend that the requirements in today's proposal be reworked so that they are closer in scope and implementation to 21 CFR Part 11, enabling the EPA FIFRA and TSCA GLP regulated entities to develop a single compliance program that will satisfy both EPA and FDA electronic records requirements. Again, SQA urges EPA to exercise caution in applying 21 CFR Part 11 requirements across the broad range of Title 40 programs in a 'one size fits all' manner.
- (20) Comment 2: We recommend that the conversion of paper records to electronic forms be addressed.

Justification: If electronic records are to be the storage medium of choice in the future, acceptable methods for the conversion of paper documents to an electronic form must be developed. Since some predicate rules require retention for many years, conversion, retention and migration parameters should be defined. Even if current technologies do limit this ability CROMERRR should not disallow this as an option so long as the appropriate criteria are met.

- C. 6 System Archives. EPA also proposes to require that electronic document receiving systems maintain the contents of the *transaction record* described above.... EPA seeks comments on these archiving criteria, and especially on whether there are any issues raised by the need to maintain the *copy of record* which includes electronic signatures over long periods of time.
- (21) **Comment 1:** Ensuring the trustworthiness of electronic signatures over long periods of time is addressed in "Records Management Guidance for Agencies Implementing Electronic Signature Technologies," National Archives and Records Administration, October 18, 2000. In particular, the NARA has recommended two possible approaches in section 4.3 of this document:

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> One approach: An Agency may choose to maintain adequate documentation of the records' validity, such as trust verification records, gathered at or near the time of record signing. This approach requires agencies to retain contextual information to adequately document the processes in place at the time the record was electronically-signed, along with the electronically-signed record itself. The additional contextual information must be retained for as long as the electronically-signed record is retained. Thus the Agency preserves the signature's validity and meets the adequacy of documentation requirements by retaining the contextual information that documented the validity of the electronic signature at the time the record was signed. Maintaining adequate documentation of validity gathered at or near the time of record signing may be preferable for records that have permanent or long-term retention times since it is less dependent on technology and much more easily maintained as technology evolves over time. However, using this approach, the signature name may not remain readable over time because of bit-wise deterioration in the record or as a result of technological obsolescence. Agencies must ensure that for permanent records the printed name of the signer and the date when the signature was executed be included as part of any human readable form (such as electronic display or printout) of the electronic record.

Another approach: An Agency may choose to maintain the ability to re-validate digital signatures. The re-validation approach requires agencies to retain the capability to revalidate the digital signature, along with the electronically-signed record itself. The information necessary for revalidation (i.e., the public key used to validate the signature, the certificate related to that key, and the certificate revocation list from the certificate authority that corresponds to the time of signing) must be retained for as long as the digitally-signed record is retained. Both contextual and structural information of the record must be retained, as described in Section 4.2. This approach is potentially more burdensome, particularly for digitally-signed records with long retention needs, due to issues of hardware and software obsolescence. If an Agency chooses this approach for permanent records, it must contact NARA to discuss what they will need to do to transfer the records to NARA. As in the first approach, the Agency must ensure that the printed name of the electronic signer and the date when the signature was executed be included as part of any human readable form (such as electronic display or printout) of the electronic record.

We recommend adoption of the first approach.

Justification: (1) Adoption of this approach would be consistent with NARA recommendations; and (2) there are currently no known technological solutions that adequately support revalidation of digitally-signed records over long retention periods.

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- 4. E. What are the Costs and Benefits Associated with Today's Proposal? 1. Scope and Method. ... EPA is seeking comment from reviewers on alternative record-keeping approaches and on EPA's assumption that facilities choosing to submit data via XML or EDI will not acquire new hardware or software.
- (22) **Comment 1:** The final costs and benefits of the proposal depend on business needs. The cost of XML software is low, but as e-commerce grows, more facilities will be investing in EDI software and the cost of reporting electronically to the Agency will be reduced. Some authors (see "Why use XML?" at www.geocities.com/WallStreet/Floor/5815/) believe the most efficient way to handle this data exchange is to combine XML with an existing EDI if the business is utilizing this technology.

Justification: Adobe has developed a plug-in called IStructure for Adobe Acrobat that permits exporting the content of a PDF document to a database for online publication. According to the information on the Adobe website, the entire Adobe package, which includes the plug-in, is \$999. As most users are already using Adobe Acrobat, the plug-in may actually cost less. If the user opts to use EDI software, that technology will have to be purchased, whereas the cost appears minimal if XML is used without EDI.

- V. B. 2 The CDX Registration Process 9. You provide personal and business information that may include some of the following items your name, home address, e-mail address, social security number, telephone number, credit card number, driver's license information, employer's address, common name of your employer, legal company name of your employer, name and telephone number of your direct manager, and name and telephone number of a human resource contact.
- (23) **Comment 1:** It may not be feasible (or legal under various state and federal statutes) or reasonable to force individuals to divulge social security numbers, driver license numbers, and personal credit card information. Some individuals may even refuse to provide personal, private and confidential information. Alternative means of verification of identity should be considered.

Justification: We believe there may be acceptable alternate means of verification that do not include a requirement to divulge personal confidential information for the purpose of identity verification.

- VI. E. Unfunded Mandates Reform Act, paragraph 3 "...this rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local and ... or in the private sector in any one year...."
- (24) **Comment 1:** We ask EPA to re-assess the financial burden of complying with this rule to the entire regulated community.

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Justification: We believe the assertion that the rule is "voluntary" and that this rule will not mandate excess expenditures exists in theory only. The reality is that electronic systems are already being used extensively by the regulated community. In addition, a single facility may be using many different commercially available systems that were not designed to meet the proposed requirements set forth in this rule. Since nearly all of the estimated 1.2 million facilities to be affected by this rule are currently collecting electronic data and creating electronic records a new financial burden analysis is required. In order to comply with this rule, the analysis needs to take into consideration that expenditures in gap and risk analyses, upgrading software, purchasing new systems where others cannot comply and implementing costly migration schemes will place a sizeable burden on industry. If we look to the FDA implementation of 21 CFR Part 11 much has been discussed and written regarding the high cost involved (as much as \$100 million to the pharmaceutical industry according to one White Paper, 21 CFR Part 11, Achieving Business Benefits, published by Accenture) in attempting to implement the rule and overcome difficulties that the regulated industry encountered.

§3.1 Scope:

(25) Comment 1: This paragraph describes the conditions for satisfying requirements that include "maintenance of electronic records." We recommend including "generation" of records also.

Justification: While "generation" of records may be implied, including generation of records would improve consistency in implementation.

§3.3 Definitions, Electronic document

(26) **Comment 1:** This definition excludes documents submitted on such magnetic media as diskettes, compact disks or tapes. Does this mean that electronic documents on such media can be submitted, and are not required to comply with the requirements for electronic records as set forth in CROMERRR? Additionally, we recommend changing the term "electronic document" to "electronically submitted document."

It is not clear to us what is meant by "exclusion." Is a facility that is excluded from the reporting requirements of CROMERRR also exempt from the record-keeping requirements until such time as an EPA program announces they are prepared to accept electronic reports?

Justification: Clarification of this and the other issues raised in this comment will reduce potential delays in implementation and remove the burden from the Agency of repeatedly clarifying the issue.

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§3.3 Definitions, Electronic document receiving system

(27) **Comment 1:** This definition describes receiving systems without mentioning state programs or certified systems. Please clarify whether all electronic document receiving systems must be certified, regardless of whether they are part of a state program or belong to private industry.

Justification: Clarification of which systems must be certified will reduce potential delays in implementation and remove the burden from the Agency of repeatedly clarifying the issue.

§3.3 Definitions

(28) Comment 1: Digital signature is not defined. We recommend defining the term in the context of its various potential uses. For submissions to the CDX it appears digital signatures will be based on Public Key Infrastructure. Will the same standard be used for the electronic signatures for data collection and individual reports?

Justification: The term "digital signature" is used in both the Preamble and the Proposed Rule. Clarification of the Agency's definition associated with the term will reduce confusion and facilitate implementation of compliance plans by the regulated community.

- §3.3 Definitions Electronic record-retention system means any set of apparatus, procedures, software, records or documentation used to retain exact electronic copies of electronic records and electronic documents.
- (29) Comment 1: EPA FIFRA, 40 CFR 169.2 (k) concerning data and records requires all "original" data to be maintained for the length of the product registration (which may be greater than 30 years). We recommend OEI contact the EPA FIFRA office in charge of 40 CFR Part 169 and clarify if the migration of records, meeting CROMERRR's criterion for the migration, will be acceptable as maintaining "original" records and that "original" paper records retention, implicit in 40 CFR Part 169, is nullified by the issuance of CROMERRR.

Justification: With the data requirements in EPA FIFRA 40 CFR 169.2(k), it is unclear whether migrated data, as implied in CROMERRR, would meet the requirements of 40 CFR Part 169.

(30) **Comment 2:** We recommend modifying the definition for "electronic record-retention systems" from "used to retain exact electronic copies" to "used to maintain accurate and complete copies."

Justification: This wording change would clarify the acceptability of migrated data.

(31) **Comment 3:** The definition for electronic record retention system seems to exclude "original" records. Please clarify EPA's intent regarding electronic systems that generate original data.

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Justification: It is currently unclear whether original data collection systems are included in the definition of electronic record retention systems.

- §3.3 Definitions Electronic signature device means a code or other mechanism that is used to create electronic signatures. Where the device is used to create an individual's electronic signature, then the code or mechanism must uniquely belong to or be associated with or assigned to that individual. Where the device is used to create an organization's electronic signature, then the code or mechanism must uniquely belong to or be associated with or assigned to that organization.
- (32) **Comment 1:** This definition implies that a device is *required* to create electronic signatures. Please clarify what is meant by "device" and whether such device is required for electronic signatures that are used in the maintenance of electronic records required by EPA FIFRA and TSCA GLP, electronic records that are not submitted to the Agency electronically. For example, would a UserID and password be considered an electronic signature device, or is a device something more complex?

Justification: The definition of an electronic signature device as a "code" or "other mechanism" causes confusion and requires clarification. Clearly stated definitions will allow regulated entities to develop appropriate plans to meet compliance expectations in the specified timeframe.

- §3.10 (b) Electronic documents submitted to EPA to satisfy a federal environmental reporting requirement or otherwise substitute for a paper submission permitted or required by a federal environmental program must be submitted to either: (1) EPA's Central Data Exchange; or (2): Another EPA electronic document receipt system that the Administrator may designate for the receipt of specified submissions.
- (33) **Comment 1:** We recommend that, for EPA FIFRA and TSCA GLP submissions, the current submitter registration process be declared acceptable by CROMERRR on an individual company basis that submits the registration on behalf of all companies (which could be many) that may have participated in the studies included in the submission.

Justification: In the case of EPA FIFRA and TSCA GLP reports, there will be many electronic signatures in one report, and many reports in one FIFRA or TSCA registration filing with EPA. By making the submitter registration process acceptable on an individual company basis for EPA FIFRA and TSCA GLP registration filings, there will be far less tracking, need for resources, and burden on both EPA's and industry's part. This will still result in placing responsibility for the filing and compliance with CROMERRR on the individual company.

(34) Comment 2: We recommend that CROMERRR establish a different CDX prototype process for handling EPA FIFRA and TSCA GLP submissions.

Justification: This is suggested because of the size of a typical EPA FIFRA or TSCA GLP submission (e.g., a typical FIFRA submission may be 56,000 pages or 1,300 megabytes of data).

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(35) Comment 3: We recommend that provisions be made for CDX to accommodate CBI submissions from EPA FIFRA and TSCA GLP submitters.

Justification: This is suggested because it is very possible that CBI will be part of the EPA FIFRA and TSCA GLP submissions. Protection of CBI is important to both EPA and to the submitters of the information.

- $\S 3.10$ (b) (2) Electronic signature must meet the validation requirements of the electronic document receiving system to which it is submitted.
- (36) Comment 1: Please clarify the meaning of the term "validation." When considered in the context of electronic systems and electronic records, the term "validation" generally applies to a process used to ensure consistent intended performance of a computer system. It is recommended that the term "validation" should be included in §3.3 Definitions.

Justification: This could be confusing to submitters. Clearly stated definitions will allow regulated entities to develop appropriate plans to meet compliance expectations in the specified timeframe.

§3.20 How will EPA provide notice of changes to the Central Data Exchange?

(37) Comment 1: We recommend that EPA clarify the backup procedure for the Central Data Exchange and the procedures that will be followed when the system is not operational (down).

Justification: Although the rule addresses notification of the public for planned changes to the CDX or another EPA electronic document receiving system, it does not indicate how the CDX system will be backed up to protect against the loss of data/reports submitted to EPA. Since electronic documents can only be submitted to this system, there should be procedures in place to let submitters know when the system is down and how submissions should be made during that time period (e.g., use of another receiving system) as well as notification of users when the system is operational again.

§3.100 (a)(1) Generate and maintain accurate and complete electronic records and documents in a form that may not be altered without detection.

(38) Comment 1: Please clarify any requirements, in addition to a secure audit trail, necessary to satisfy this requirement.

Justification: According to this section of the rule, an electronic record or electronic document will satisfy a record-keeping requirement of an EPA administered federal environmental program under this title only if it is generated and maintained by an electronic record retention system as specified under this subsection. EPA should clarify any additional controls that it would consider necessary to preserve the integrity of electronic records and documents. The burden and cost to industry in implementing controls should be taken into consideration when determining the need for such practices in the final rule.

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§3.100(a)(2) Maintain all electronic records and electronic documents without alteration for the entirety of the required period of record retention;

(39) Comment 1: §3.100(a)(2) seems to be contradictory to §3.100(a)(6), which requires audit trails for changes to data.

Justification: It would seem that documents that have already been signed and submitted electronically should be maintained without alteration. However, electronic records may be changed as new data are obtained or when errors have been identified. In the latter case, an audit trail would indicate the changes as specified in §3.100(a)(6).

§3.100(a)(3) ...accurate and complete copiesin both human readable and electronic form...for the entirety of the required period of record retention.

(40) Comment 1: EPA FIFRA and TSCA GLP retention times can be very long—e.g., from 10 to about 30 years—whereas FDA GLP (21 CFR Part 58) retention times are 2 to 5 years after submission to FDA in an application for research or marketing permit (in the case of submitting a New Drug Application [NDA], this also can be a very long period of time). We recommend identifying a more liberal approach to records that must be retained for extended periods of time. If migration of electronic records and reports is a solution to recovery over the record retention period, we recommend that OEI undertake a cost benefit analysis, before CROMERRR is finalized, on the impact of migrating data under CROMERRR in EPA FIFRA and TSCA GLP environments.

We additionally recommend that EPA consider working with industry representatives, the EPA Office of Enforcement and Compliance, as well as FDA to resolve the issue of long-term recovery of electronic records and reports.

Justification: This presents a major difference between what is required for FDA's 21 CFR Part 11 on electronic records and what is required of industry by CROMERRR. It may mean that migration of the electronic records and reports, hardware, software, etc., will be required, since retaining obsolete hardware and software is impractical and in some cases impossible for recovery over the extended retention periods required by some EPA or FDA predicate rules. Migration requires major acceptance testing and validation activity. This would be a massive and costly exercise to simply migrate the registration documents for only one chemical entity. Maintaining the meta data during migration is also a very difficult task.

The use of data loggers (the most commonly used are Hobos and Stowaways) is widespread in the regulated community. These miniature loggers can log temperature of soil, water, air, relative humidity, barometric pressure and light intensity and can be used for all types of studies, monitoring of weather or building storage conditions, and other scientific applications.

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Hobos/Stowaways operate on a lithium type battery, which typically lasts around two years at which time it is replaced by the user. Hobos/Stowaways begin logging immediately upon being launched using the software provided with the data logger. Reading out a logger stops the logging cycle, and it is not started again until it has been launched through the computer. To read out the logger, it is connected to the computer and the data are transferred from the Hobo/Stowaway to the computer, usually in a graph. There is no way for someone to read the Hobo/Stowaway data until the data are transferred to this graph.

CROMERRR requires that we produce accurate and complete copies of an electronic record and render these copies readily available, in both human readable and electronic form throughout the entire retention period. The retention time may be lengthy, since regulations state that all "original" data should be maintained for the length of the product registration (which may be greater than 30 years).

There are several problems inherent to the retention of electronic data generated by Hobos/Stowaways. First, there is the problem of retention of original electronic raw data. CROMERRR requires that we retain the original electronic raw data; however, in this case, the original raw data are actually in the Hobo/Stowaway unit and is not accessible to anyone. Since these units are battery operated, it is almost impossible to retain this data in its "original" form. If one attempted to archive a Hobo/Stowaway unit, someone would have to replace the batteries on a regular basis so that the data would not be lost due to lack of power. There is no guarantee that the Hobo/Stowaway unit could actually be saved for any length of time since they are designed to transfer data to a graph for human use and not designed for long term data retention. A graph allows for easy retention of the downloaded data in an electronic form.

Archiving a data logger would be similar to archiving a thermometer. The thermometer contains original raw data. However, it is useless unless it is recorded in some manner. The temperature is recorded and referred to as the original raw data. With a data logger, the information is downloaded into a spreadsheet and referred to as the original raw data.

Second, there is the problem of retaining original data in human readable form. The Hobo unit does not capture original electronic data in a human readable form. The data only becomes "human readable" after it is downloaded into a graph. Until the data are transferred to a graph, there is no way to modify these records. Transferring the records to the graph allows for an audit trail beginning with the downloading of the data from the Hobo/Stowaway. Use of a graph allows the entire electronic record to be preserved without modification in its human readable form and in its electronic form.

Third, there is the problem of expenses. A middle of the line Stowaway costs \$140. If you archived one of these units, you would then have to replace the original unit with a new unit. This could be very expensive for facilities that use a large number of units. However, the graph download from the data logger can be retained electronically and with very few problems and little expense.

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(41) **Comment 2:** Please define "off-site" review. Does this mean access to a network by Agency reviewers?

Justification: The ability to reproduce an electronic copy of a record or subset of records for off-site review can be a major implementation hurdle especially with more complex electronic record-keeping systems. For example, the ability to export a record may be straightforward but exporting accompanying meta data, electronic signatures, and audit trails may be problematic and in some cases, impossible. It may take significant time and programming resources to do a full export. It will also be difficult for companies to assess their ability to comply with this requirement without more specifications from the EPA on what type of file exports they will be able to review off-site. More detail on what is required to meet this requirement is needed.

§3.100(a)(4) Provide that any electronic record or electronic document bearing an electronic signature contain the name of the signatory, the date and time of signature, and any information that explains the meaning of the affixed signature;

(42) **Comment 1:** Please clarify whether all electronic records or only those bearing an electronic signature must contain the specified descriptors.

Justification: This clarification would explain what is meant by electronic records. Clearly stated definitions will allow regulated entities to develop appropriate plans to meet compliance expectations in the specified timeframe.

(43) Comment 2: Suggest adding the word "printed" before the phrase "name of signatory."

Justification: This clarification would explain the required form of the signatory's name.

(44) **Comment 3:** Please further explain the "time" requirement. Is it hour, or hour and minute, and is the local time where the work is being performed required?

Justification: This clarification in wording related to the "time" definition would dispel possible confusion about interpretation of this issue.

(45) Comment 4: Change §3.2000(f)(2), which references "The precise date and time (based on the system clock)," to agree with §3.100(a)(4).

Justification: Signatures may be stored locally or at a central location in another time zone. The proposed change would permit each company to document, in its own procedures, the relationship between system time stamps and the time zone in which a signature is executed.

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- §3.100(a)(6) Use secure, computer-generated, time-stamped audit trails that automatically record the date and time of operator entries and actions that create, modify, or delete electronic records or documents;
- (46) Comment 1: Please further explain the "time" requirement. Is it hour, or hour and minute, and is the local time where the work is being performed required?

Justification: This clarification in wording related to the "time" definition would dispel possible confusion about interpretation of this issue. We recommend the recording of the date and time (hour: minute) local to the operator entries and actions. Clearly stated definitions will allow regulated entities to develop appropriate plans to meet compliance expectations in the specified timeframe.

(47) **Comment 2:** Please consider changing the following phrase from "audit trails that automatically..." to "audit trails that, after final approval, automatically..." or to "audit trails for approved electronic records or documents that automatically...."

Justification: With EPA FIFRA and TSCA GLPs, electronic records and documents have to be "committed" before they become an "officially accepted" electronic record or document. This clarification in wording would allow this process to continue.

- §3.100(a)(8): ...records and documents are searchable and retrievable for reference and secondary uses... for the entirety of the required period of record retention.
- (48) Comment 1: Please define "secondary uses," and clarify what is meant by "available for legal proceedings and third party disclosures."

Justification: It is unclear why industry must assure availability of records for legal proceedings, third party disclosures, and other government uses other than assuring to the Agency the reliability and trustworthiness of the records. In addition, if the regulations require records and documents to be searchable and retrievable for secondary uses, then the industry must verify this and validate the system or process. Therefore, it is important to identify the "secondary uses."

- §3.100 (a)(9)(ii): Related meta data can be transferred to a new system.
- (49) Comment 1: We recommend that OEI undertake a cost benefit analysis of the impact of migrating data under CROMERRR in EPA FIFRA and TSCA GLP environments. It is further recommended that the scope, attributes and purpose of the related meta data should be defined.

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Justification: It is likely that migration of electronic records during the entire record retention requirement time will be necessary, since under EPA FIFRA and TSCA GLPs, retention periods vary from 10 to about 30 years. This required retention time is considerably greater than for FDA GLP (21 CFR Part 58) records and should be considered when specifying migration and functionality for retained records. The requirement to migrate electronic records would also require validation of the migration system and/or process to assure accuracy, reliability and integrity of the data migration. The cost analysis of the migration requirement should include the cost of validation.

It is necessary to identify the scope, attributes and purpose of the related meta data to help the industry to determine how to meet this requirement. Additionally, when migrating electronic records and documents to a new computer system, there is often no reasonable place to receive the meta data from the old system.

§3.100 (a) (9) (iii): Functionality necessary for use of records can be reproduced in a new system;

(50) **Comment 1:** It is our contention that the functionality required by archival material is for retrieval of records rather than for use of records. Therefore, we recommend a wording change from "functionality necessary for use of records can be reproduced in a new system" to "functionality necessary for the retrieval of the records can be utilized in a new system."

Justification: The suggested wording change would be a more accurate reflection of retrieving the records in a new system. Please consider the record retention times (potentially as long as 30 or more years) and the changing technology that might place an unreasonable burden on industry to comply with such a requirement.

§3.100(b) Computer systems (including hardware and software), controls, and attendant documentation maintained under this Part must be readily available for, and subject to, Agency inspection.

(51) **Comment 1:** Change the wording to "Current computer systems (including hardware and software), controls, and attendant documentation..."

Justification: The resources required to archive obsolete software and hardware, and assure that they will function properly at some future date, far outweighs any benefit derived.

Please do not require maintenance/retention of legacy systems. The transfer/migration of data from one system to another should be acceptable.

(52) Comment 2: Change control is a desired mechanism for assuring that a system is managed in a way that assures changes to the system have been properly assessed and implemented. Does the term "controls" relate to change control? Please clarify.

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Justification: There is confusion over the meaning of "controls." Clearly stated definitions will allow regulated entities to develop appropriate plans to meet compliance expectations in the specified timeframe.

Please define "controls" in the definitions section of the regulation or provide a description of what is meant by this term in this section of the regulation.

(53) **Comment 3:** Legacy systems are not addressed with respect to acceptable electronic records. We recommend that CROMERRR address what to do with legacy computer systems and related records. This could be accomplished by inclusion either in the preamble or in the Rule itself.

Justification: There will be a tremendous negative economic cost impact if regulated industry must maintain legacy computer systems, for the entire record retention requirement time, as evidence of how electronic records or reports were available at the time of collection.

§3.2000 What are the criteria for acceptable electronic document receiving systems?

(54) **Comment 1:** Please clarify if and how the criteria for electronic document receiving systems do or do not apply to all electronic records systems, even those that will not be used to submit an electronic document through an electronic document receiving system.

Justification: The electronic document receiving system may be classified according to FDA's 21 CFR Part 11 as an "open" system requiring application of encryption technology, submitter registration and electronic signature certification processes. However, we do not believe that such rigorous controls are necessary to ensure the integrity of data and attributability of electronic signatures applied to electronic records in "closed" systems where the electronic records are not submitted to the EPA. The organization responsible for the content of the electronic records has control of system access. Please consider defining "closed" and "open" systems and the controls associated with each.

§3.2000 (a)(1) Have strong and effective protections against unauthorized access to the system;

(55) **Comment 1:** More guidance on the minimum requirements needed to meet the "strong and effective" criteria is needed.

Justification: There may be a broad interpretation across industry of what constitutes "strong and effective protection" against unauthorized system access or foreseeable corruption or system compromise. Furthermore, "strong and effective protection against unauthorized system access" may not be possible under certain types of operating systems (e.g., Windows 98). Clearly stated definitions will allow regulated entities to develop appropriate plans to meet compliance expectations in the specified timeframe.

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- §3.2000 (a) (2) An acceptable electronic document receiving system must: ...have strong and effective protections against the unauthorized use of any electronic signature on electronic documents submitted or received;
- (56) **Comment 1:** What sort of oversight will be employed to ensure these criteria are met? Please clarify whose responsibility it is to ensure that unauthorized use does not occur. Please describe the types of systems which will be used to monitor for "unauthorized use" activities. Clearly stated definitions will allow regulated entities to develop appropriate plans to meet compliance expectations in the specified timeframe.

Justification: Technology changes are rapid and constant. Industry or EPA may be the defined entity that ensures that these criteria are met for "unauthorized use" and will be responsible for monitoring all data transmissions and storage. The end result may impose a large and unreasonable amount of resource expenditures for either party.

- §3.2000 (a) (4) Prevent modification of an electronic document once an electronic signature has been applied. (c) (5) Ensures that it is impossible to modify an electronic document without detection...
- (57) **Comment 1:** This requirement prohibits modification of an electronic document after an electronic signature has been affixed.

Justification: We agree that an electronic record should not be modified after having been signed without the knowledge of the signatory; however, if circumstances arise where the electronic record requires revision, an automatically generated audit trail should be allowed for both the modifications and the repeated act of signing the electronic record to document adequately the changes.

- § 3.2000 (a)(6) Ensure that the system clock is accurate and protected from tampering or other compromise.
- (58) Comment 1: We recommend more detail as to what the Agency requires concerning the accuracy of the system clock and protection from tampering or other compromises.

Justification: For the system clock accuracy, each company should be allowed to document, in its own procedures, the relationship between the system clock time and its accuracy and the time zone in which a signature is executed. Protecting the clock from tampering may be difficult depending on the operating system and whether it is a client-based or server-based system. The requirements described in the PREAMBLE V (The Central Data Exchange (CDX) Section 3; The CDX Architecture) should be made uniform throughout the proposed CROMERRR.

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§3.2000 (b) Validity of data

(59) Comment 1: This section refers to ensuring that the electronic document was actually submitted by the authorized signature holder. It appears this requirement applies to electronic documents submitted through document receiving systems. Please clarify how this requirement will be applied to electronic documents that contain numerous signatures, such as EPA FIFRA or TSCA GLP regulatory submissions that contain numerous reports with multiple signatures from potentially multiple sites in each report.

Justification: It is difficult to envision how this requirement would be applied to the EPA FIFRA or TSCA GLP regulatory submissions without causing undo hardship and unreasonable costs on submitting organizations. This is especially relevant if these requirements extend to small businesses that could be part of the multiple sites, referred to in this comment. Clarification will allow regulated entities to develop appropriate plans to meet compliance expectations in the specified timeframe.

§3.2000 (d) Submitter registration process

(60) Comment 1: CROMERRR describes submission of electronic reports or electronic data through a certification process for state programs and systems. During the July 2000, CROMERRR Open Meeting in Washington, DC, it was stated that no certification would be required for electronic reporting and record-keeping systems maintained by companies, operating under EPA FIFRA and TSCA GLPs, which submit reports directly to EPA.

When companies submit reports directly to EPA, we recommend that EPA clarify the issue of a CROMERRR certification process to be used or not used by companies operating under EPA FIFRA and TSCA GLPs.

Justification: It is unclear what CROMERRR certification process is to be used or not used by companies submitting reports directly to EPA when they are operating under EPA FIFRA and TSCA GLPs.

(61) Comment 2: Has EPA conducted a rigorous cost/benefit estimation for the electronic submitter and signature registration process?

Justification: The cost to industry to implement a compliance program under EPA FIFRA and TSCA GLPs has been substantial, with estimates of 20 to 30% over conducting a nonclinical study without compliance to GLPs. Therefore, if an additional CROMERRR certification process cost is to be added to the cost of doing business, industry needs to know EPA's estimates of the added cost and related benefits.

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§3.2000 (d)(4)(i) ... automatic and immediate revocation... any actual or apparent violation...

(62) **Comment 1:** This section provides for an automatic revocation for actual or "apparent" violation of electronic signature agreement. We recommend that a process be defined for investigating and verifying "apparent" violations prior to any action that is taken.

Justification: While this may be appropriate for an actual violation, we believe this approach could result in unwarranted submission delays and possible loss of revenues if an "apparent violation" is the result of inaccurate or faulty reporting. Investigating and verifying "apparent" violations prior to any revocation action would help alleviate potential submission delays and revenue losses.

§3.2000 (d)(5) Require that the registrant periodically renew his or her electronic signature agreement.

(63) Comment 1: We recommend that EPA delete section 3.2000 (d)(5).

Justification: If appropriate verifications had been conducted when the acceptable electronic document receiving system and submitter registration process was established, an electronic signature should be valid for the length of employment. Therefore, the need to renew periodically or re-issue electronic signatures is not warranted. If this requirement is not deleted by EPA, the cost of going through the renewal process should be determined prior to specifying a particular period of time for renewal and this information included in the cost/benefit analysis for implementation of CROMERRR.

§3.2000(e) Electronic signature/certification scenario:

(64) Comment 1: The certification of signatures with EPA is a very complex process compared to FDA 21 CFR Part 11 requirements. We recognize that these criteria apply to electronic documents submitted to electronic document receiving systems, but believe that clarification is needed around electronic signatures that are applied to electronic records within a "closed" system, one where access is controlled by the persons responsible for the content of the electronic records. EPA proposes to require that an electronic document receiving system must validate only electronic signatures that have been affixed after: 1) the submitter has scrolled through on-screen pages that present all the data to be certified in a familiar, human-readable format (§3.2000(e)(1)(i))." EPA is encouraged to meet with representatives of the EPA FIFRA and TSCA GLP regulated community, as well as representatives from the EPA Office of Compliance, in order to assess and understand the volume of data involved with submission of documents for registration. The volume of documents included in a FIFRA or TSCA GLP submission may make it both resource intensive and cost prohibitive.

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Justification: We believe the complex electronic signature certification scenario described for electronic document receiving systems is burdensome and unnecessary for the integrity of data in closed systems. Furthermore, we believe that a process similar to that set forth in 21 CFR Part 11, where companies can send notification to FDA and have policies in place within their organizations that hold people accountable for their electronic signatures will suffice for the purposes of electronic signatures applied to electronic records in "closed" systems, as described above. We also believe that EPA should adopt this FDA approach in CROMERRR. Scrolling through on-screen pages would probably require significant modification to most electronic document receiving systems, thereby imposing substantial cost and delay in ability to implement CROMERRR-compliant systems. It is doubtful that this requirement would significantly add to the evidentiary value of the signature. Furthermore, this requirement appears to force a higher standard on signed electronic documents than what exists for paper documents.

This requirement is more stringent than current requirements and would produce an undue burden on the submitter when submissions that entail thousands of pieces of information are electronically transmitted to EPA.

§3.2000(g)(2)(i) Maintain the records... for at least the same length of time as would be required for a paper document that corresponds to the received electronic document, and in a way that can be demonstrated to have preserved them in their entirety without alteration since the time of their creation.

(65) **Comment 1:** We recommend that EPA specifically omit digital signatures from the maintenance requirement.

Justification: While the proposed EPA requirements are consistent with those published by the FDA in 21 CFR Part 11, the retention times set by the predicate rules are very different, and it is doubtful whether maintenance criteria for electronic records over extended retention periods can also be met for digital signatures. For example, David Fillingham notes that "Handwritten signatures can be verified in perpetuity, whereas digital signatures will likely become unverifiable after ten years or so due to data processing equipment and cryptographic standards obsolescence, certificate expiration, and other factors." (A Comparison of Digital and Handwritten Signatures, Paper for MIT 6.805/STS085: Ethics and Law on the Electronic Frontier, Fall 1997) - see http://swissnet.ai.mit.edu/6805/student-papers/fall97-papers/fillingham-sig.html). With EPA FIFRA or TSCA GLP required retention periods varying from about 10 to 30 years, deletion of "digital signatures" from the maintenance requirement is especially relevant.